

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

<p>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</p> <hr/> <p>THIS DOCUMENT RELATES TO ALL CASES</p>	<p>Master File No. 2:12-MD-02327 MDL No. 2327</p> <p>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</p>
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**DEFENDANT'S RESPONSE, REQUEST FOR MEET-AND-CONFER, AND IN THE
ALTERNATIVE, MOTION FOR PROTECTIVE ORDER REGARDING PLAINTIFFS'
"SECOND AMENDED NOTICE TO TAKE ORAL DEPOSITION OF DEFENDANT
ETHICON LLC THROUGH DESIGNATED WITNESS(ES)" AND
ACCOMPANYING REQUEST FOR PRODUCTION OF DOCUMENTS**

Defendant Ethicon, LLC ("Ethicon") hereby responds to Plaintiffs' "Second Amended Notice to Take Oral Deposition of Defendant Ethicon, LLC Through Designated Witness(es)" (the "Notice"). The Notice was filed and served on May 30, 2014 [Document 1205].

Defendant states that the Notice seeks testimony and documents regarding Ethicon, LLC, an entity that, pursuant to Plaintiffs' motion, was recently removed from the Long Form Complaint and the Short Form and Amended Short Form Complaints in this MDL. See Pretrial Order #117 [Document 1196]. Defendant further states that the order provided that "[a]t a later time, the court will initiate a show cause process regarding Ethicon, LLC in existing cases." *Id.* In addition, Defendant states that the majority of topics in the Notice, including but not limited to topics that primarily seek the identification of specific documents and/or the contents thereof, are more appropriately the subject of written discovery. As to Topics I, II and VI in particular, without any adoptive admissions, Defendant refers Plaintiffs to the documents identified in its Responses to Plaintiffs' Requests for Production, which are set out below. In addition,

Defendant agrees to meet-and-confer with Plaintiffs regarding the proper scope of testimony, if any, regarding the topics in this Notice.

To the extent that Defendant and Plaintiffs are unable to reach agreement as part of the meet-and-confer process, Defendant conditionally moves for a protective order on the grounds set forth herein.

Ethicon, LLC objects to the Notice and its accompanying document requests on the grounds that Ethicon, LLC has been removed from the Long Form Complaint and the Short Form and Amended Short Form Complaints. *See* Pretrial Order # 117 [Document 1196]. In addition, Defendant objects to the Deposition Topics on the grounds that they (a) are vague and ambiguous, (b) are overly broad, (c) seek testimony that is neither relevant to the subject matter of this action nor reasonably calculated to lead to the discovery of admissible evidence, (d) are unduly burdensome and oppressive, and (e) are duplicative of extensive discovery, including depositions, already taken. Defendant further objects to the Deposition Topics on the grounds that the majority of substantive topics, including but not limited to topics that primarily seek the identification of specific documents and/or the contents thereof, are more appropriately the subject of written discovery. Defendant additionally objects to the Definitions set forth in the Notice on the grounds that such Definitions are improper in the context of a deposition notice seeking oral testimony and, if taken literally, would create burdens on any witness that are not contemplated by Fed. R. Civ. P. 30(b)(6).

The responses and objections contained herein are made without in any way waiving or intending to waive—but on the contrary reserving and intending to reserve—the right at any time to revise, supplement, correct, or add to these objections and responses.

RESPONSES AND OBJECTIONS TO DOCUMENT REQUESTS

Document Request No. 1: All documents relied upon by the deponent in preparing for this deposition.

Responses and Objections to Document Request No. 1: Defendant objects that this request seeks information protected by the attorney work product doctrine. *See, e.g., Hickman v. Taylor*, 329 U.S. 495, 511 (1947); *In re Allen*, 106 F.3d 582, 608 (4th Cir. 1997) (observing that “choice and arrangement [of documents in witness’s personnel file by counsel for witness] constitutes opinion work product because [counsel’s] selection and compilation of these particular documents reveals her thought processes and theories regarding this litigation”); *Rhodes v. E.I du Pont de Nemours & Co.*, 558 F. Supp. 2d 660, 671 (S.D. W. Va. 2008) (Goodwin, C.J.) (“Courts acknowledge that the document selection process represents the mental impressions of the party’s counsel and is protected work product.” (internal quotation marks and alterations omitted)).

Subject to and without waiving any objection, Defendant has a reasonable and good faith belief that responsive documents, if any, would have been identified in connection with the collection process and have been produced. To the extent that additional documents, if any, are identified during the process of preparing for any scheduled depositions, Defendant will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

Document Request No. 2: All documents reflecting correspondence between the FDA and Ethicon LLC regarding mesh products or facilities and procedures involved in the manufacture of mesh products or polypropylene sutures.

Responses and Objections to Document Request No. 2: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 3: All current and former product specifications for mesh products and polypropylene sutures including draft copies.

Responses and Objections to Document Request No. 3: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding

manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 4: Ethicon LLC's quality manual, quality policy, written procedures for management review, quality audits and quality plan as well as minutes and notes management review meetings regarding these documents.

Responses and Objections to Document Request No. 4: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 5: Any documents indicating or discussing deviation from product specifications, including but not limited to: fraying, bunching, curling, degradation, fading, crumbling, folding, toxicity or sizing of mesh products or polypropylene sutures.

Responses and Objections to Document Request No. 5: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the

objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 6: Records of mesh product that was rejected and destroyed or otherwise disposed for not meeting product specifications.

Responses and Objections to Document Request No. 6: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 7: All agreements between Ethicon LLC and third parties or consultants related to the supply of mesh products or polypropylene resin for use in humans.

Responses and Objections to Document Request No. 7: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 8: All documents related to whether the use of polypropylene mesh, sutures, or resin is safe for use in humans.

Responses and Objections to Document Request No. 8: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding

manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 9: Any material safety data sheets for polypropylene or product safety data sheets for polypropylene in your possession from the date you first started manufacturing your mesh products or polypropylene sutures.

Responses and Objections to Document Request No. 9: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 10: Any material safety data sheets or product safety sheets for the raw materials or component parts of your mesh products and polypropylene sutures from the date you first started manufacturing your mesh products.

Responses and Objections to Document Request No. 10: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the

objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 11: All communications with any vendors, suppliers or other third parties related to the supply of materials or component parts for the manufacture of the mesh products.

Responses and Objections to Document Request No. 11: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 12: All documentation regarding Corrective and Preventative Actions ("CAPAs") and Product Quality Issues ("PQIs") regarding the mesh products

manufactured, handled, or processed by you, including but not limited to memoranda, draft, and final reports of such actions and issues and all communications between Ethicon LLC and other Johnson & Johnson entities and third parties regarding such actions and issues.

Responses and Objections to Document Request No. 12: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 13: Any records reflecting the inspection, maintenance or sterilization for any equipment or facilities used by Ethicon LLC in the production of mesh products or polypropylene sutures, including the ownership of such equipment and communications with any third parties contracted to perform inspection, maintenance, or sterilization of said equipment or facilities.

Responses and Objections to Document Request No. 13: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the

objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Document Request No. 14: Any records reflecting the measurement and maintenance of temperature and humidity within the facilities utilized by Ethicon LLC in the manufacture, storage, or transportation of mesh products, polypropylene sutures, and polypropylene resin.

Responses and Objections to Document Request No. 14: Defendant objects to this Request on the grounds that it is irrelevant, overly broad and unduly burdensome, particularly in light of Ethicon, LLC's removal from the Long Form Complaint and Short Form and Amended Short Form Complaints and impending dismissal. Subject to and without waiver of the objections stated herein, and pursuant to the Protective Order entered by the Court in this matter, Defendant refers Plaintiffs to documents previously produced by Defendants, which include manufacturing and quality documents regarding Ethicon's pelvic mesh products that have been located in connection with reasonable searches, including of Ethicon, LLC, where appropriate. In addition, Defendant states that the appropriate scope of discovery regarding manufacturing-related documents relating to its pelvic mesh products has been the subject of an ongoing meet-and-confer process with Plaintiffs' counsel.

Respectfully submitted,

ETHICON, INC. AND
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SOUTHERN DISTRICT OF WEST VIRGINIA
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CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on June 9, 2014, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas

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